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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,879	04/25/2006	Bent Karsten Jakobsen	006090.00017	9328
22907 7590 12/20/2007 BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051			EXAMINER WESSENDORF, TERESA D	
			ART UNIT 1639	PAPER NUMBER
			MAIL DATE 12/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/532,879	JAKOBSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6,55-59 and 86-89 is/are pending in the application.
- 4a) Of the above claim(s) 55-59,88 and 89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,86 and 87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicants' election of Group I and the species of phage particle and dimeric TCR in the reply filed on 10/25/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 55-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/25/07.

### ***Status of the Claims***

Claims 1, 6, 55-59 and 86-89 are pending in the instant application.

Claims 55-59 and 88-89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. [Note that claims 88-89 are drawn to a modified or mutant form of a TCR bound phage. However, claim 1 does not recite a mutant or a modified form of said TCR.

Accordingly, these claims to a mutant (i.e., by substitution) have been withdrawn from consideration.]

Claims 1, 6 and 86-87 are under examination.

**Specification**

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

**Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 6 and 86-89 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 drawn to a phage particle displaying on its surface a dimeric T-cell receptor(TCR), or a single chain TCR (scTCR) polypeptide, wherein the scTCR or dTCR comprises an interchain disulfide bond linking residues of constant domain sequences would read on a naturally occurring phage particle which

displays on its surface a dimer of T-cell receptor i.e., alpha beta TCR). (See Xu et al, Immunity at page 37, col. 1).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection).

Claim 86 drawn to a phage particle of claim 1 wherein the interchain disulfide bond has no equivalent in native T cell receptors is not supported by the original disclosure. Likewise, claim 87, phage particle of claim 6 wherein the interchain disulfide bond has no equivalent in native T cell receptors is also not supported in the as-filed specification. The original

disclosure does not support said negative limitations. MPEP 714.02 clearly states that applicants point out where in the specification support for the new limitations appear in the as-filed specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 86 and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite in the recitation of "no equivalent" in the native TCR of the interchain disulfide bonds. It is not clear as what the claim language encompasses, especially in the absence of positive support in the specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 86-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Weidanz [(J Immunol Methods)(I) or (WO 99/18129)(II).]

Weidanz (I) discloses at e.g., page 59, abstract, a bacteriophage display on its surface a dimeric T cell receptor comprising an interchain disulfide bond linking residues of constant domain sequences. See also page 60, col. 1 and col. 2 and page 73, col. 1.

Claim 6 linking of TCR at the C-terminus to the N-end of phage is disclosed at page 73, col. 2.

Claims 86 and 87 which recite a disulfide bond would be inherent to the TCR dimer which is formed by the disulfide bonds between the alpha and beta TCR region.

Weidanz (II), throughout the patent, basically discloses the same dimer TCR as disclosed at e.g., the abstract.



Claims 1, 6 and 86-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Nissim et al (WO 01/62908).

Nissim discloses in e.g., the abstract, a phage-display, comprising recombinant phages each comprising a vector (V) having a polynucleotide (P1) which codes for a T-cell receptor (TCR) recognition element, and/or a mutation and variant, in which the vector expresses a recombinant TCR recognition element from each of the recombinant phages.

See also page 8.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

T. D. Wessendorf  
Primary Examiner

12/17/07